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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/827,133

04/19/2004

Michael S. Allen

6704-29

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02/27/2007

RUDEN, MCCLOSKEY, SMITH, SCHUSTER & RUSSELL, P.A.

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.:

10/827,133

Applicant(s)

ALLEN ET AL.

Examiner

Jennifer Dunston

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9, 10, 15, 16, 18-23, 25, 26 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3, 9, 15, 16, 18-23, 25, 26 and 30 is/are allowed.
- 6) ☒ Claim(s) 2, 4 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the amendment, filed 11/27/2006, in which claims 5-8, 11-14, 17, 24, 27-29 and 31 were canceled, and claims 2, 4 and 10 were amended. Currently, claims 1-4, 9, 10, 15, 16, 18-23, 25, 26 and 30 are pending and under consideration.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2, 4 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** This is a new rejection, necessitated by the amendment of claims 2, 4 and 10 in the reply filed 11/27/2006.

Claim 2 is drawn to a nucleic acid construct comprising LuxA modified with a tail-specific protease sequence and LuxB modified with a PEST sequence. Claim 4 is drawn to a nucleic acid construct comprising LuxA modified with a tail-specific protease sequence and LuxB modified with a PEST sequence, further comprising LuxC, LuxD, and LuxE. Claim 10 is

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drawn to nucleic acid construct comprising a modified LuxA comprising a tail specific protease sequence selected from the group consisting of SEQ ID NOS: 8, 9 and 10 and LuxB modified with a PEST sequence. Thus, the claims are drawn to the specific combination of LuxA modified with a tail-specific protease sequence and LuxB modified with a PEST sequence.

The specification teaches that the *LucCDABE* operon contains five genes necessary for self-sustained bioluminescence in bacteria: *LuxAB* is a luciferase, which catalyzes the light-producing reaction; *LuxCE* is a multi-component enzyme that converts myristic acid to a fatty aldehyde substrate for the light-producing reaction; and *LuxD* is a transferase that assists *LuxCE* (e.g. paragraph bridging pages 5-6). The specification teaches nucleic acid constructs comprising *luxA* and *luxB* genes (e.g. Table 2). The specification describes plasmid vectors where only one of *LuxA* or *LuxB* is mutated with a tail-specific protease sequence or where both *LuxA* and *LuxB* have a tail-specific protease modification (e.g. Table 2). The tail-specific proteases sequences are disclosed as functional in bacteria (e.g. Example 3-Lux-based Bacterial Bioreporters Exhibiting Reduced Bioluminescent Half Life). The specification discloses the PEST modification for use in eukaryotic cells such as yeast (e.g. Example 4- Methods For Construction of Lux-based Eukaryotic Bioreporter in Yeast; Example 5- Lux-based Eukaryotic Bioreporters Exhibiting Reduced Bioluminescent Half Life). The specification does not describe a nucleic acid construct comprising *LuxA* modified with a tail-specific protease and *LuxB* modified with a PEST sequence. This combination of *Lux* sequences is not supported by the specification, claims or drawings as originally filed. The response does not point to portions of the specification, claims or drawings as originally filed as support for the claimed combinations of modified *LuxA* and modified *LuxB* sequences.

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Therefore, claims 2, 4 and 10 represent a departure from the specification, claims and drawings as originally filed.

Response to Arguments - 35 USC § 112

The rejection of claims 2, 6, 10, 11 and 31 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 11/27/2006.

The rejection of claims 2 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 11/27/2006.

The rejection of claim 4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) has been withdrawn in view of Applicant's amendment to the claims. However, the amendment of claim 4 in the reply filed 11/27/2006 has necessitated a new rejection of claim 4 as failing to comply with the written description requirement (see above).

Conclusion

Claims 1, 3, 9, 15-16, 18-23, 25-26 and 30 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER

